

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Derek O'Hagan  
 Application No.: 10/633,475  
 Date Filed: 07/31/2003  
 Title: MICROPARTICLES WITH ADSORBENT SURFACES, METHODS OF MAKING SAME AND USES THEREOF  
 Group Art Unit: 1642  
 Examiner.: Unassigned  
 Atty. Docket: PP01388.211

## INFORMATION DISCLOSURE STATEMENT (IDS)

Mail Stop DD  
 Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, VA 22313-1450

SIR:

In accordance with 37 C.F.R. §1.56 and in compliance with 37 C.F.R. §§1.97 and 1.98, the references listed on attached Form PTO/SB/08 and/or subsequently identified herein, are being submitted herewith for consideration by the United States Patent and Trademark Office.

I. COPIES

- a. ☐ A legible copy of (i) each U.S. and foreign patents; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed, is included herewith.
- b. ☒ Any patents, publications or other information which are listed on PTO/SB/08 which are not enclosed herewith were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. §120:

U.S. Serial NumberU.S. Filing Date

09/581,772

06/15/2000

II. CONCISE EXPLANATION OF THE RELEVANCE (check at least one box)

- a. ☒ Except as may be indicated below in (b) of this section, all of the patents, publications or other information are in the English language (concise explanation not required).
- b. ☐ A concise explanation of the relevance of all patents, publications or other information listed that is not in the English language is as follows:
- c. ☐ The following additional information is provided for the Examiner's consideration:

III. ☒ CROSS REFERENCE TO RELATED APPLICATION(S)

The Examiner is advised that the following co-pending application(s) contain(s) subject matter that may be related to the present application. By bringing this (these) applications to the Examiner's attention, Applicant(s) does(do) not waive the confidentiality provisions of 35 U.S.C. §122.

Serial No.Filing DateArt Unit

09/581,772

06/15/2000

1642

10/357,303

02/03/2003

1642

**FEEs**

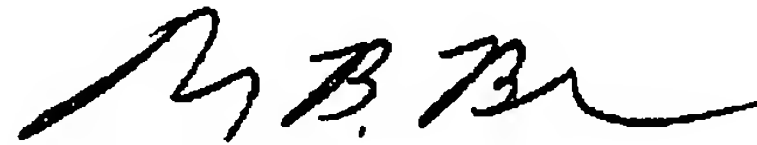
- IV. ☒ **THIS IDS IS BEING FILED UNDER 37 C.F.R. §1.97(b):** (check one box)
- a. ☐ within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d) (37 C.F.R. §1.97(b)(1)). No fee or statement is required.
  - b. ☐ within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. §1.97(b)(2)). No fee or statement is required.
  - c. ☒ before the mailing date of a first Office Action on the merits (37 C.F.R. §1.97(b)(3)). No fee or statement is required.
  - d. ☐ before the mailing date of a first Office Action after the filing of a request for continued examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.
- V. ☐ **THIS IDS IS BEING FILED UNDER 37 C.F.R. §1.97(c):** (check one box)  
before the mailing date of any of a Final Office Action under 37 C.F.R. §1.113, a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in the application (See 37 C.F.R. §1.97(c)).
- a. ☐ No statement; therefore, charge deposit account 50-1047 the fee set forth in 37 C.F.R. §1.17(p).
  - b. ☐ See the statement below. No fee is required.
- VI. ☐ **THIS IDS IS BEING FILED UNDER 37 C.F.R. §1.97(d):**  
on or before payment of the issue fee and is accompanied by the following:
- 1) a statement under 37 C.F.R. §1.97(e) as provided below; and
  - 2) charge deposit account 50-1047 the petition fee set forth in §1.17(p).
- VII. ☐ **STATEMENT UNDER 37 C.F.R. §1.97(e)** (check only one box, if applicable)  
The undersigned hereby states that
- a. ☐ each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of IDS; or
  - b. ☐ no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and to knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the IDS was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement, or
  - c. ☐ some of the items of information contained in the IDS were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the IDS was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement.
- VIII. **PAYMENT OF FEES**
- ☐ A check in the amount of \_\_\_\_\_ is enclosed for the above-identified fee(s).
  - ☐ Please charge Deposit Account No. 50-1047 in the amount of \$180.00 for the above-indicated fee(s).

- ☒ If Applicant has overlooked any additional fees, or if any overpayment has been made, the Commissioner is hereby authorized to credit or debit Deposit Account 50-1047.
- ☐ Two Copies of this paper are attached for Deposit Account charges and debits.

It is Applicant(s)' opinion that the claims presently on file patently distinguish the present invention from each of these references. The above references are being cited only in the interests of candor and without any admission that they constitute statutory prior art or contain matter which anticipates the invention or which would render the same obvious, either singly or in a combination, to a person of ordinary skill in the art.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule (with a petition if necessary) and charge the appropriate fee to Deposit Account No. 50-1047.

Respectfully submitted,



David B. Bonham  
Attorney for Applicant(s)  
Reg. No. 34,297  
Tel. 703-433-0510  
Fax 703-433-2362

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Enclosures: ☒ PTO/SB/08  
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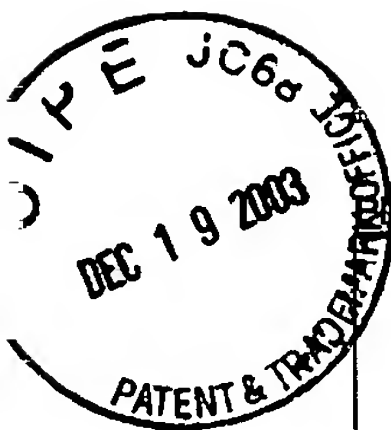
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Joanne Ryan

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Docket No.: PP01388.211

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Substitute for form 1449A/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<i>Complete if Known</i>	
				Application Number	10/633,475
				Filing Date	07/31/2003
				First Named Inventor	Derek O'Hagan
				Group Art Unit	1642
				Examiner Name	Unassigned
Sheet	1	of	3	Attorney Docket Number	PP01388.211

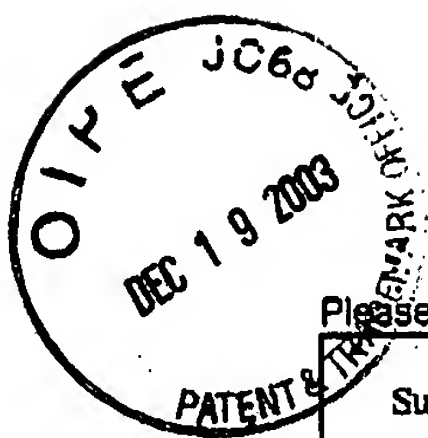
Examiner Initials*	Cite No. 1	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM- DD-YYYY
		Number	Class/Subclass		
	1.	5,643,605	424/279.1	Cleland et al.	07/01/1997
	2.	5,902,565	424/1.29	Cox et al.	05/11/1999
	3.	4,413,057	424/244.1	Carlo et al.	11/01/1983
	4.	5,010,183	435/262	Macfarlane	04/23/1991
	5.	6,086,901	424/283.1	O'Hagan et al.	07/11/2000
	6.	5,871,747	424/208.1	Gengoux-Sedlik et al.	02/16/1999
	7.	5,869,103	424/501	Yeh et al.	02/09/1999
	8.	5,783,567	514/44	Hedley et al.	07/21/1998
	9.	5,830,430	424/1.21	Unger et al.	11/03/1998
	10.	5,630,922	204/499	Eswarakrishnan et al.	05/20/1997
	11.	4,534,996	427/498	Rembaum et al.	08/13/1985
	12.	5,714,354	435/101	Arnold et al.	02/03/1998

Examiner Initials*	Cite No. 1	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T
		Office <sup>3</sup>	Number <sup>4</sup>	Class/Subclass			
	1.	WO	96/20698	A61K 9/51	University of Michigan	07/11/1996	
	2.	WO	95/24929		Brown University	09/1995	
	3.	WO	98/33487	A61K 9/16	Chiron Corporation	08/06/1998	
	4.	WO	98/10750	A61K 9/16		03/19/1998	
	5.	WO	96/20698	A61K 9/51		07/11/1996	
	6.	WO	94/28879	A61K9/16		12/22/1994	
	7.	WO	94/15635	A61K 39/385		07/21/1994	
	8.	WO	97/02810	A61K 9/16	University of Nottingham	01/30/1997	
	9.	WO	97/24447	C12N 15/63	Chiron Viagene, Inc.	07/10/1997	

Examiner Signature		Date Considered	
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation, if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English Language Translation is attached.



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Sheet	2	of	3	Attorney Docket Number	PP01388.211

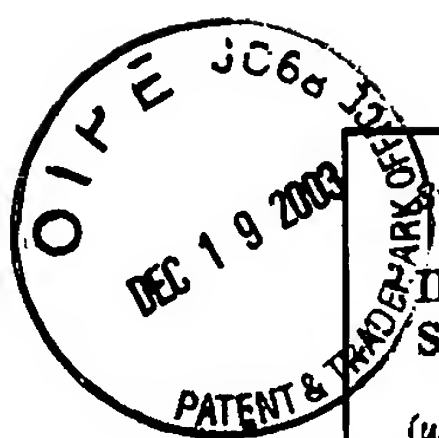
OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	1.	Moore et al., <i>Vaccine</i> , Vol. 13, no. 18, 1995, pp. 1741-1749	
	2.	Haynes et al., <i>AIDS Research and Human Retroviruses</i> , Vol. 10, Supplement 2, 1994, pp. S42-S45.	
	3.	A.G.A. Coombes et al., "Single Dose, Polymeric, Microparticle-based Vaccines: The Influence of Formulation Conditions on the Magnitude and Duration of the Immune Response to a Protein Antigen," <i>Vaccine</i> , Vol. 14, no. 15, 1996, pp. 1429-1438.	
	4.	Jacqueline D. Duncan et al., "Poly(lactide-co-glycolide) Microencapsulation of Vaccines for Mucosal Immunization," <i>Mucosal Vaccines</i> (Academic Press, 1996), pp. 159-173.	
	5.	John H. Eldridge et al., "Biodegradable and Biocompatible Poly(DL-Lactide-Co-Glycolide) Microspheres as an Adjuvant for Staphylococcal Enterotoxin B Toxoid Which Enhances the Level of Toxin-Neutralizing Antibodies," <i>Infection and Immunity</i> , Vol. 59, no. 9, 1991, pp. 2978-2986.	
	6.	John H. Eldridge et al., "New Advances in Vaccine Delivery Systems," <i>Seminars in Hematology</i> , Vol. 30, no. 4, 1993, pp. 16-25.	
	7.	Deborah A. Higgins et al., "MF 59 Adjuvant Enhances the Immunogenicity of Influenza Vaccine in Both Young and Old Mice," <i>Vaccine</i> , Vol. 14, no. 6, 1996, pp. 478-484.	
	8.	Ying Men et al., "Induction of a Cytotoxic T Lymphocyte Response by Immunization with a Malaria Specific CTL Peptide Entrapped in Biodegradable Polymer Microspheres," <i>Vaccine</i> , Vol. 15, no. 12-13, 1997, pp. 1405-1412.	
	9.	Ryusuke Nakaoka et al., "Enhanced Antibody Production Through Sustained Antigen Release from Biodegradable Granules," <i>Journal of Controlled Release</i> , Vol. 37, 1995, pp. 215-224.	

Examiner Signature		Date Considered	
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Sheet	3	of	3	Attorney Docket Number	PP01388.211

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T <sup>2</sup>
	10.	D.T. O'Hagan et al., "Long-Term Antibody Responses in Mice Following Subcutaneous Immunization with Ovalbumin Entrapped in Biodegradable Particles," <i>Vaccine</i> , Vol. 11, no. 9, 1993, pp. 965-969.		
	11.	D.T. O'Hagan, "Biodegradable Microparticles for Oral Immunization," <i>Vaccine</i> , vol. 11, 1993, pp. 149-154.		
	12.	Michael F. Powell et al., eds., <i>Vaccine Design: The Subunit and Adjuvant Approach</i> (New York: Plenum Press, 1995), p 183.		
	13.	Hongkee Sah et al., "Continuous Release of Proteins from Biodegradable Microparticles and In Vivo Evaluation of Their Potential as a Vaccine Adjuvant," <i>Journal of Controlled Release</i> , Vol. 35, 1995, pp. 137-144.		
	14.	H.M. Vordermeier et al., "Synthetic Delivery System for Tuberculosis Vaccines: Immunological Evaluation of the <i>M. tuberculosis</i> 38 kDa Protein Entrapped in Biodegradable PLG Microparticles," Vol. 13, no. 16, 1995, pp. 1576-1582.		
	15.	Bertling et al., "Liposomes, Viral Capsids, and Nanoparticles as DNA Carriers," <i>Biotechnology and Applied Biochemistry</i> , Vol. 13, 1991, pp. 390-405.		
	16.	Christine Chavany et al., "Adsorption of Oligonucleotides onto Polyisohexylcyanoacrylate Nanoparticles Protects Them Against Nucleases and Increases Their Cellular Uptake," <i>Pharmaceutical Research</i> , Vol. 11, no. 9 (1994), pp. 1370-1378.		
	17.	Elias Fattal et al., "Biodegradable Polyalkylcyanoacrylate Nanoparticles for the Delivery of Oligonucleotides," <i>Journal of Controlled Release</i> , Vol. 53 (1998), pp. 137-143.		

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